

1**ORTHOPAEDIC FIXATION PLATE****BACKGROUND OF THE INVENTION****1. Field of the Invention**

The present invention relates to a plate for use as part of an external fixation device, and more particularly to a unique hole pattern within the plate.

2. General Background and Description of the Prior Art

Traditional circular ring external fixation devices consist of Ilizarov-type devices that are based on a circumferential external fixator system disclosed by G. A. Ilizarov during the early 1950's. The Ilizarov system includes at least two rings or "halos" that encircle a patient's body member (e.g., a patient's leg), connecting rods extending between the two rings, transfixion pins that extend through the patient's boney structure, and connectors for connecting the transfixion pins to the rings. Use of the Ilizarov system to deal with angulation, translation and rotation is disclosed in "Basic Ilizarov Techniques," *Techniques in Orthopaedics*®, Vol. 5, No. 4, December 1990, pages 55-59.

The Ilizarov system provides an external fixation frame that allows for gradual correction along and about six axes; however such frames require many parts and are relatively complicated to build and use in a clinical situation. In addition, often orthopedic external fixators such as Ilizarov frames must be modified after their initial application. Such modification may be necessary to convert from one correctional axis to another. Alternatively, such modifications may allow conversion from an initial adjustment type of frame to a weight bearing type frame, since some of the correctional configurations are not stable enough for weight bearing.

The rings used in the Ilizarov devices include a plurality of spaced apertures or holes that allow for the attachment of various accessories to the device. The pattern of Ilizarov ring holes is primarily determined as a function of the diameter of the ring. Conventional wisdom teaches that for any given diameter, the ring should include the maximum number of equally spaced arcuately positioned holes. Those skilled in the art believe that such hole positioning provides the surgeon with the greatest degree of flexibility in constructing the often times complicated and elaborate Ilizarov frame configuration. The Ilizarov ring holes, although equally spaced about a circle, are positioned such that the location of any given hole relative to another hole on additional rings attached thereto, is completely irrelevant.

Applicants have recently developed a new external fixation device known as the Taylor Spatial Frame™ external fixator. This device is described and claimed in the allowed U.S. patent application Ser. No. 08/782,731 entitled "Orthopaedic Fixation Device." In addition, applicants have developed a unique method of using the Taylor Spatial Frame™ fixator that is the subject of allowed U.S. patent application Ser. No. 08/726,713 entitled "Method of Using An Orthopaedic Fixation Device." Both of these patent applications are incorporated herein by reference. As disclosed in these prior patents, the Taylor Spatial Frame™ fixator, in its preferred embodiment, consists of two ring plates interconnected by six adjustable length struts. This device can be configured to correct virtually an infinite number of deformities, each of which would have otherwise required the construction of a specific custom Ilizarov frame.

As with the prior art Ilizarov fixator, the Taylor Spatial Frame™ fixator plates include a plurality of spaced apertures or holes therethrough for attaching accessories to the device. In addition, the plates include plurality of cavities or

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holes for attachment of the struts to the rings. Applicants have now developed a unique hole placement scheme for the Taylor Spatial FRAME™ fixator rings. This unique hole placement scheme takes advantage of the unique nature of the Taylor Spatial Frame™ fixator and the unique method of using the same, and provides substantial advantages over the unsystematically placed hole patterns utilized in Ilizarov rings.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a novel external fixation plate that can be used as part of the Taylor Spatial FRAME™ fixator, and facilitates the unique method of using the Taylor Spatial Frame™ fixator.

It is a further object of the present invention to provide a novel external fixation plate that is easy to manufacture, and simplifies the fixator construction process.

It is a further object of the present invention to provide a novel external fixation plate that offers various clinical advantages over prior art designs by providing a convenient frame of reference to aid a surgeon in preoperative planning and surgical application of the device.

It is a further object of the present invention to provide a system of plates, wherein each plate within the system offers unique symmetrical properties and common hole spacing.

It is a further object of the present invention to provide a hole scheme for an external fixation plate that provides a clear geometric relationship between the holes on such plate relative to other holes on the same plate or holes on attached plates.

These and other objects are realized by a fixation plate that includes a plurality of attachment mechanisms located thereon. The attachment mechanism preferably consists of a plurality of equally spaced and symmetrically positioned holes. In accordance with a preferred embodiment, the present invention includes a plate having a body portion that includes a plurality of substantially equally spaced apertures or holes positioned arcuately therein. The holes are designed to facilitate attachment of a plurality of adjustable length struts that interconnect one or more plates, and the attachment of various accessories to the plates. The strut holes and the accessory holes may be indistinguishable or they may be different. The arrangement of the holes provides triple symmetry, and preferably 2x3 symmetry. Based on a defined geometric relationship between plate holes, a system of plates can be designed that offer triple symmetry or 2x3 symmetry.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top view of a plate in accordance with one embodiment of the present invention.

FIG. 2 is a perspective view of an external fixation device incorporating one embodiment of the novel plate of the present invention.

FIG. 3 is an enlarged view of a portion of one of the plates shown in FIG. 2.

FIG. 4 is a perspective view of an external fixation device incorporating an alternative embodiment of the novel plate of the present invention.

FIG. 5 is an enlarged view of a portion of a plate of the present invention, and illustrates the geometric relationship between two adjacent holes.

FIG. 6 is a top view of a plate in accordance with an alternative embodiment of the present invention.

FIG. 7 is a top view of a plate in accordance with an alternative embodiment of the present invention.

FIG. 8 is a top view of a plate in accordance with an alternative embodiment of the present invention.

FIG. 9 is a top view of a plate in accordance with an alternative embodiment of the present invention.

FIG. 10 is a top view of a plate in accordance with an alternative embodiment of the present invention.

FIG. 11 is a perspective view of an external fixation device incorporating an alternative embodiment of the novel plate of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Because of the unique nature of the Taylor Spatial FRAME™ fixator and the unique method of using the Taylor Spatial FRAME™ fixator, the position of a given hole relative to another hole, either on the same plate or a different plate, is very important. Indeed, we have found that the correct positioning of the holes simplifies the manufacturing and device construction processes, simplifies the method of using the device by simplifying the geometric analysis of the system, and provides a number of clinical advantages.

FIG. 1 illustrates a fixator plate in accordance with a preferred embodiment of the present invention. The plate 2 includes a circular body portion 4 fabricated from a suitably strong and rigid material such as a metal, alloy, plastic, composite, or ceramic. The body portion 4 includes a plurality of substantially equally spaced apertures or holes 8 positioned arcuately therein. In the specific embodiment shown in FIG. 1, the center of the holes 8 form a complete circle as illustrated by the broken line 10, wherein the circle has a center c and a radius of r. It is important to note that each hole 8 may have a different diameter or shape as long as the center of the hole substantially intersects with the circle 10.

As illustrated in FIG. 2 and FIG. 4, the holes 8 are designed to facilitate attachment of a plurality of adjustable length struts 20 that interconnect one or more plates 2. In accordance with the preferred embodiment of the present invention, six struts 20 are used to interconnect two plates 2. In addition, the holes 8 are designed to facilitate attachment of various accessories to the plate 2, such as for example, wires (not shown), clamps 24, pins 26, additional plates, etc. In accordance with the embodiment shown in FIG. 1 and FIG. 4, the strut holes and the accessory holes are indistinguishable, i.e. any hole 8 can be selected to serve as a strut hole or an accessory hole. In accordance with an alternative embodiment, as shown in FIG. 2, the accessory holes 14 and the strut holes 12 are different.

As illustrated in FIG. 2, in accordance with one embodiment of the present invention, each plate 2 has three actual strut attachment positions 16. In addition, each plate 2 includes three additional strut positions 18 that are not actually used. The unused strut positions 18 are included to provide a 2x3 symmetrical design, which is discussed in greater detail below. In the preferred embodiment of the invention as shown in FIG. 2, the used strut attachment holes 16 should be positioned approximately 120° from one another so as to form a substantially equilateral triangle. Similarly, the unused strut attachment holes 18 should be positioned approximately 120° from one another so as to form a second substantially equilateral triangle. The two overlapping triangles are illustrated by broken lines in FIG. 1, and are designated triangle A and triangle B. Alternatively,

one or more strut attachment holes 16, 18 can deviate slightly from its ideal 120° position. Such deviation, however, should be less than 30°, but preferably no more than 15°, and ideally less than 6°.

Unlike the unsystematically positioning of prior art Ilizarov ring holes, the holes 8 in the present device are preferably strategically positioned within plate 2 to provide 2x3 symmetry throughout a complete system of plates. 2x3 symmetry is achieved when the holes are positioned such that the plate can be rotated in increments of 180° about a first axis and increments of 120° about a second axis, and each time maintain identical hole positions. For example, the plate 2 can be rotated 180° about an axis passing through center c and within the plane of the plate 2, i.e. the x axis shown in FIG. 2. Such a rotation would essentially flip plate 2 over. For both of the two possible positions, the hole pattern within plate 2 would be identical. This characteristic represents the "2" of the 2x3 symmetry. Similarly, plate 2 can be rotated in increments of 120° about an axis perpendicular to the plate and passing through center c, i.e. the y axis shown in FIG. 2. There are three possible positions that the plate 2 could assume by making 120° rotations about the y axis. Following each rotation, however, the resulting hole positions will remain unchanged. This characteristic represents the "3" of the 2x3 symmetry. In accordance with the present invention, a system of plates is provided, as described hereinbelow, wherein each plate within the system offers at least triple symmetry (i.e., the "3" symmetry), and preferably each plate offers complete 2x3 symmetry.

In order to obtain the 2x3 symmetry, as noted above, plate 2 should include two sets of three strut holes with each strut hole 12 positioned about 60° apart in a circle. In addition, 2x3 symmetry requires that the total number of holes 8 (including both strut holes 12 and accessory holes 14) be a multiple of six (6). For triple symmetry alone, however, the total number of holes 8 need only be a multiple of three (3). Furthermore, the accessory holes should be equally spaced. One skilled in the art will appreciate that asymmetrical "dummy" holes can be added to the plate 2. Such a plate would nonetheless fall within the scope of the present invention.

As illustrated in FIG. 3, the spacing between the accessory holes 14 can be measured in terms of the arc length l_{arc} along circle 10 or in terms of the chord length l_{chord} . In accordance with the preferred embodiment, the distance between holes 14 is measured by the chord length l_{chord} , and such lengths are equal. Furthermore, the distance between each strut hole 12 and its adjacent accessory hole 14 need not be the same as the distance between two adjacent accessory holes 14. As illustrated in FIG. 3, this distance can be measured along arc as d_{arc} or along the chord as d_{chord} . In accordance with the preferred embodiment of the present invention, the chord lengths between every accessory hole 14 and its adjacent accessory hole 14 or strut hole 12 are equal, that is $d_{chord}=l_{chord}$. In addition, the chord length is should be greater than about 0.475 inch, but preferably is between about 0.48–0.52 inch, and most preferably equal to about 0.5 inch.

In accordance with the specific embodiment of the present invention illustrated in FIG. 2, the exact positions of the holes 8 are determined as follows. The process is very different from the unsystematic positioning of the holes in prior art Ilizarov devices, which starts with determining the ring diameter. The Taylor Spatial Frame™ fixator hole positions are determined by first determining the hole spacing, and then determining the number of holes that will be used. The present hole positioning scheme starts with the

number of holes because it is important that the number be a multiple of three to maintain the requisite symmetry. Once the distance between the holes and the number of holes is determined, the diameter of the ring is defined by the formula:

$$\text{diameter} = l \left(\sqrt{\left(\frac{1}{\tan^2\left(\frac{180}{N}\right)} + 1 \right)} \right)$$

where 1 is the chord distance between holes 8, and N is the total number of holes.

As illustrated in FIG. 5, for any given two adjacent holes 8, the angle between the holes is θ , and the chord between the holes is l. An isosceles triangle T is formed by connecting the two adjacent plate holes 8 and the center c of the circle 10. If a line 28 having length b is formed in the middle of the isosceles triangle T, two right triangles are formed, and the following relationships exists:

$$b^2 + (l/2)^2 = r^2$$

and

$$\tan(1/2\theta) = \frac{l/2}{b}$$

where r represents the radius of the circle 10. If for convenience we define $v = \frac{1}{2}l$ and $Q = \tan(\frac{1}{2}\theta)$, the following relationships can be derived from the above equations:

From Equation (1)

$$b^2 = r^2 - v^2$$

$$b = \sqrt{r^2 - v^2}$$

From Equation (2)

$$Q = \frac{v}{b}$$

Combining (4) and (5)

$$Q = \frac{v}{\sqrt{r^2 - v^2}}$$

solving for the radius r gives:

$$r = \sqrt{\frac{v^2}{Q^2} + v^2}$$

or

$$r = \sqrt{v^2 \left(\frac{1}{Q^2} + 1 \right)}$$

Therefore, for any plate having N holes and a chord distance of 1 between adjacent holes, the diameter of the circle that defines the hole locations can be expressed mathematically as

$$\text{diameter} = 2 \left(\sqrt{\left(\frac{l}{2} \right)^2 \left(\frac{1}{\tan^2(1/2\theta)} + 1 \right)} \right)$$

-continued

$$= l \left(\sqrt{\left(\frac{1}{\tan^2(1/2\theta)} + 1 \right)} \right) \quad (9)$$

If the total number of holes in the ring will be N, then $\theta = 360^\circ/N$, and

$$\text{diameter} = l \left(\sqrt{\left(\frac{1}{\tan^2\left(\frac{180}{N}\right)} + 1 \right)} \right) \quad (10)$$

Using the relationship defined in equation 10, a system of rings including a variety of ring diameters can be developed wherein each ring has triple symmetry and the hole spacing for each ring is the same. The following table illustrates such a system wherein the hole spacing is 0.5 inch:

TABLE I

| | Chord Length (l) (inches) | Number of Holes (N) | Diameter (inches) | angle (θ) (degrees) |
|----|------------------------------|---------------------|----------------------|---------------------------------|
| 25 | 0.5 | 3 | 0.5774 | 120 |
| | 0.5 | 6 | 1.0000 | 60 |
| | 0.5 | 9 | 1.4619 | 40 |
| | 0.5 | 12 | 1.9319 | 30 |
| | 0.5 | 15 | 2.4049 | 24 |
| | 0.5 | 18 | 2.8794 | 20 |
| | 0.5 | 21 | 3.3548 | 17.143 |
| | 0.5 | 24 | 3.8306 | 15 |
| | 0.5 | 27 | 4.3069 | 13.333 |
| | 0.5 | 30 | 4.7834 | 12 |
| | 0.5 | 33 | 5.2601 | 10.909 |
| | 0.5 | 36 | 5.7369 | 10 |
| | 0.5 | 39 | 6.2138 | 9.231 |
| | 0.5 | 42 | 6.6907 | 8.571 |
| | 0.5 | 45 | 7.1678 | 8 |
| | 0.5 | 48 | 7.6449 | 7.5 |
| | 0.5 | 51 | 8.1220 | 7.059 |
| | 0.5 | 54 | 8.5992 | 6.667 |
| | 0.5 | 57 | 9.0764 | 6.316 |
| | 0.5 | 60 | 9.5537 | 6 |
| | 0.5 | 63 | 10.0309 | 5.714286 |
| | 0.5 | 66 | 10.5082 | 5.454545 |
| | 0.5 | 69 | 10.9855 | 5.217391 |
| | 0.5 | 72 | 11.4628 | 5 |
| | 0.5 | 75 | 11.9401 | 4.8 |
| | 0.5 | 78 | 12.4174 | 4.615385 |
| | 0.5 | 81 | 12.8948 | 4.444444 |
| | 0.5 | 84 | 13.3721 | 4.285714 |
| | 0.5 | 87 | 13.8495 | 4.137931 |
| | 0.5 | 90 | 14.3269 | 4 |
| | 0.5 | 93 | 14.8042 | 3.870968 |
| | 0.5 | 96 | 15.2816 | 3.75 |
| | 0.5 | 99 | 15.7590 | 3.636364 |
| | 0.5 | 102 | 16.2364 | 3.529412 |
| | 0.5 | 105 | 16.7138 | 3.428571 |
| | 0.5 | 108 | 17.1912 | 3.333333 |
| | 0.5 | 111 | 17.6686 | 3.243243 |
| | 0.5 | 114 | 18.1460 | 3.157895 |
| | 0.5 | 117 | 18.6234 | 3.076923 |
| | 0.5 | 120 | 19.1008 | 3 |
| | 0.5 | 123 | 19.5782 | 2.926829 |
| | 0.5 | 126 | 20.0556 | 2.857143 |
| | 0.5 | 129 | 20.5330 | 2.790698 |

The triple symmetry for the complete system is realized by only including rings where the numbers of holes in each plate is a multiple of three. Similarly, a system with complete 2x3 symmetry can be designed by using plates where the number of holes in each plate is a multiple of six.

As noted above, the arc length, as opposed to the chord length, between adjacent holes 8 can be fixed. If the arc

length between the holes **8** is fixed, for a given arc length k and holes N , the circumference of the circle **10** will equal $k \times N$. Therefore the diameter would be:

$$\text{diameter} = kN/\pi$$

Using this relationship, a plate system such as following can be made:

TABLE II

| Arc Length (inches) | Number of Holes | Diameter (inches) |
|---------------------|-----------------|-------------------|
| 0.5 | 6 | 0.9549 |
| 0.5 | 9 | 1.4324 |
| 0.5 | 12 | 1.9099 |
| 0.5 | 15 | 2.3873 |
| 0.5 | 18 | 2.8648 |
| 0.5 | 21 | 3.3423 |
| 0.5 | 24 | 3.8197 |
| 0.5 | 27 | 4.2972 |
| 0.5 | 30 | 4.7746 |
| 0.5 | 33 | 5.2521 |
| 0.5 | 36 | 5.7296 |
| 0.5 | 39 | 6.2070 |
| 0.5 | 42 | 6.6845 |
| 0.5 | 45 | 7.1620 |
| 0.5 | 48 | 7.6394 |
| 0.5 | 51 | 8.1169 |
| 0.5 | 54 | 8.5944 |
| 0.5 | 57 | 9.0718 |
| 0.5 | 60 | 9.5493 |
| 0.5 | 63 | 10.0268 |
| 0.5 | 66 | 10.5042 |
| 0.5 | 69 | 10.9817 |
| 0.5 | 72 | 11.4592 |
| 0.5 | 75 | 11.9366 |
| 0.5 | 78 | 12.4141 |
| 0.5 | 81 | 12.8916 |
| 0.5 | 84 | 13.3690 |
| 0.5 | 87 | 13.8465 |
| 0.5 | 90 | 14.3239 |
| 0.5 | 93 | 14.8014 |
| 0.5 | 96 | 15.2789 |
| 0.5 | 99 | 15.7563 |
| 0.5 | 102 | 16.2338 |
| 0.5 | 105 | 16.7113 |
| 0.5 | 108 | 17.1887 |
| 0.5 | 111 | 17.6662 |
| 0.5 | 114 | 18.1437 |
| 0.5 | 117 | 18.6211 |
| 0.5 | 120 | 19.0986 |
| 0.5 | 123 | 19.5761 |
| 0.5 | 126 | 20.0535 |
| 0.5 | 129 | 20.5310 |

FIG. 4 illustrates an alternative embodiment of the present invention. Unlike the embodiment illustrated in FIG. 2, the adjoining struts **20** in FIG. 4 do not connect to the plates **2** at a single common hole **8**. As a result, each plate **2** in FIG. 4 includes six (6) strut holes **32** that are connected to a strut **20**. As illustrated, the adjacent connecting strut holes **32** are separated by a single unused hole **30**. In other embodiments of the present invention, the adjacent connecting strut holes **32** may be separated by no holes or by more than one unused hole **30**. When adjacent struts **20** do not terminate at a common hole a theoretical strut hole should be determined. As illustrated in FIG. 6, the theoretical strut hole **34** is positioned along the arc of circle **10** half way between the two actual strut holes **32**, i.e. along the circle **10** at the bisector of the two actual strut holes. When adjacent struts terminate at a single strut hole as in FIG. 2, the theoretical strut hole is the actual strut hole. In accordance with the present invention, the theoretical strut holes **34** on plate **2** should form two overlapping triangles A, B in the same

manner described above regarding the embodiment illustrated in FIG. 2. As with the actual strut holes, the chords connecting the theoretical strut holes **34** preferably form two substantially equilateral triangles. The theoretical strut holes **34**, however, may deviate from their ideal 120° positions to the same extent described above with regard to actual strut holes.

The extent to which an actual strut hole **32** can deviate from its theoretical strut hole is limited. As this deviation increases, the range of movement between the two plates **2** is reduced. The reduced range limits the various configurations that the device can assume, and therefore, limits the types of deformities that can be corrected with the device. As a result, the deviation of an actual strut hole **32** from its theoretical strut hole should be less than about 30°, but can be less than 12°, and preferable no more than about 6°.

The hole spacing scheme of the present invention can be utilized to design plates having holes that do not form a complete circle. For example, a half plate or a 1/6 plate, as illustrated in FIGS. 7 and 8 respectively, can be designed. In addition, the plate itself need not be circular, as illustrated in the embodiment shown in FIG. 9.

The mathematical relationships between hole spacing, the number of holes and the diameter that are set forth above specifically relate to a hole pattern that forms a complete circle and includes equally spaced hole around the entire circle. These mathematical relationships, however, can be adapted to describe the hole pattern for a partial circle. For example, assume that you wanted n holes positioned about a partial ring that has an arc length of α° , i.e. 180° for a half ring, 90° for a quarter ring, etc. The number of such partial rings required to form a complete circle would be $360/\alpha$. The number of holes in such a theoretical circle (N) equals $n(360/\alpha)$. One would then use the number of holes for the theoretical complete ring (N) in the equations set forth above to define the hole positions needed to form the requisite partial plate.

In accordance with another embodiment of the present invention, a plate can include holes corresponding to more than one diameter within a given system. As noted above each system is defined by the hole spacing. An example is illustrated in FIG. 10 using the system defined above in Table I. The plate **2** includes two sets of holes **8**. The first set **38** includes sixty (60) holes equally spaced ($l_{\text{chord}}=0.5$ inch) along circle **10**. As indicated above in Table I, the diameter of circle **10** is 9.5537 inches, and the radius $r_1=4.7769$ inches. The second set of holes **40** consists of six groups of three holes, i.e. six partial plates. These hole are spaced along the next highest diameter within the system. Therefore, the diameter of circle **36** is 10.5082 and the radius $r_2=5.2541$. Multiple diameter plates, such as shown in FIG. 10 are very useful. In such plates, the struts can be attached at one diameter, using for example hole set **40**, and the accessories can be attached using the other diameters, using for example hole set **38**.

It is important to emphasize that although the present invention is described in terms of accessory holes and strut holes, other attachment mechanisms can be used and still fall within the scope of the present invention. For example, each hole could be replaced with a peg that would facilitate attachment of a strut or accessory. Alternatively, as illustrated in FIG. 11, the plate **42** could include one continuous circular groove **44** that traces circle **10**. Clamps **46** could be provided that attach to the groove **44** at any location. Such clamps **46** can easily be positioned to mimic the hole patterns described above. Indeed, such a plate **42** could include indicia such as markings **48** or etches **50** within the plate, that designate the hole positions described above.